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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,562	08/16/2001	Larry D. Paskar	39868/24659	5207

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EXAMINER

BOCKELMAN, MARK

ART UNIT PAPER NUMBER

3762

DATE MAILED: 05/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/931,562

Applicant(s)

PASKAR, LARRY D.

Examiner

Mark W Bockelman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 39-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 and 48-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the longitudinal axis of each curve as well as the relative curve features of claim 7, 32, 48 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Priority

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 1.53(b) as follows: The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ 2d 1077 (Fed. Cir. 1994).

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It is noted that applicant's original specification in the current application is not identical to that in the parent application 08/764,745 or its preceding parent applications. 37 CFR section 1.53 (5) requires that "Any new change must be made in the form of an amendment to the prior application as it existed prior to the filing of an application under this paragraph. Applicant's original filed specification in the current application has two new paragraphs at the top of page 4 and two more at the top of page 5 as compared to the original specification of the parent 08/764,745. In addition to being improperly filed, the new paragraphs included in the specification contain information regarding the use of imaging that is not readily apparent. In addition, applicant's claims contain new language which support is not readily apparent in the parent application. For instance, the claims now require either first and second catheter imaging steps at various shapes or imaging during shaping, neither of which was present in the original specification. While using such imaging techniques may be obvious, as stated in applicant's preliminary comments, inherency requires necessity, which has not been demonstrated.

3. This application repeats a substantial portion of prior Application No. 08/764,745, filed 12/12/96, and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Since applicant's original filing was not properly filed for achieving status as a continuing application and also introduces new matter, applicant may either delete the continuity to the parent applications or change the status of the current application to a continuation in part of the 08/764,745 parent application.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claim Rejections - 35 USC 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-38, 48-67 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sylvanowicz. USPN 5,267,982. With regard to apparatus claims 1-7 it would appear that applicant in reciting the formation of the out of plane catheter configuration during a particular period of time has formulated the limitation in the claim as a statement of intended use. In this regard, Sylvanowicz teaches an inner catheter illustrated in figure 11 (surgical element) that is situated within an outer catheter figure 10, each with preformed curves. The entire assembly of catheters is to be inserted into the body. Sylvanowicz teaches that with regard to his two different catheter configurations, the configuration in figs 1-8 has in at least one embodiment that is a standard Judkins left coronary catheter structure or a modified left Judkin structure (figs 9-14) wherein the angle defined by bend 62 is slightly larger. The curves in the Sylvanowicz catheter are remotely controllable by moving the inner catheter longitudinally with respect to the outer catheter. Angiography is specifically taught for each of the right Judkins and left Judkins coronary artery configurations with radiopaque dye which entails fluoroscopic imaging. If not inherent

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7. Claims 1-38, 48-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petruzzi USPN 4,474,174 in view of Cho USPN 5,109,830 or vice versa. Petruzzi et al teach an inner surgical element comprising a catheter with a preformed curve 56 along with a surgical instrument disposed therein, and both further disposed in an outer catheter in the form of a duodenoscope. As was well known in the art, such scoped has a two way control element 42 and 42' that allow two plane bending to traverse the alimentary tract including the small intestine region. It is not apparent to one of ordinary skill in the art that Petruzzi et al uses such two plane direction it would have been obvious to D'Amelio et al USPN 4,659,195. As can be seen in figure 1 of Petruzzi, the device of Petruzzi is used to position catheter member 56 into the ampulla of Vater which is located on the rear wall of the duodenum in a highly curved region which tends to curve towards the front of a person near the stomach and back towards the rear as well as to the left side approaching the ileum. This relative location of the ampulla of Vater is shown to some extent by Petruzzi but can better be seen in the three dimensional figure attached to this office action (Takahashi "Atlas of the Human Body"). As a result of the relative positions, it is seen as a requirement that the outer tubular member of Petruzzi must be used to position the endoscope in a left right manner relative to the page while the catheter 56 is bent and or manipulated to guide its tip into the page so as to access the ampulla of Vater. Such a manipulation requires the inner surgical element 56 60 be positioned out of the plane to the bent curved portion of the outer endoscope. It is apparent to those of ordinary skill in the art that such an out of plane configuration would be necessary in order to access the the ampulla of Vater. In

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terms of rotationally fixing the inner surgical element, It was well known to stabilize endoscopic devices including rotationally fixing and sealing the inner surgical element relative to the outer sheath body as disclosed by Cho. Petruzzi shows a first and second configuration in figure 3 that are used in catheterizing the duodenum and later the ampulla of Vater. The bends in the Petruzzi catheter as shown in figure 11 are both within 3 lengths of the smaller radii of curve. While Petruzzi does not teach the use of imaging techniques, Cho teaches the inclusion of fluoroscopic markers, which are notably absent from applicant's disclosure, and are necessary, for viewing the catheter and optical fiber members. To have included such markers on Petruzzi, or alternatively provide Cho with the controllable bending wires, would have been obvious in view of each others teachings and the fact they are accessing similar body portions.

8. Claims 1-38 and 48-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ganz et al USPN 4,430,083. Ganz et al shows in figure 12 and 13, methods for catheterizing two passageways of the lower circumflex branch using a catheter using a planar outer catheter 11a (column 7 lines 7-20) and an inner rotatable catheter 105. The figures 12 and 13 appear to show two different configurations including an out of plane configuration as the inner catheter 105b is shown in rotated position to access each branch. Takahashi is presented as showing how the branches go off in different directions requiring such an out of plane configuration. The examiner considers it obvious to provide the first treatment of figure 12 followed by a second treatment in figure 13. Ganz uses a radiopaque tip for imaging and it is inherent or obvious to provide imaging steps in the two different configurations.

9. Claims 1-38, 48-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho USPN 5,109,830. Cho teaches a method of accessing the various ducts including pancreatic, bile, common etc. and shows such an arrangement in figure 7. While figure 7 shows a duodenoscope 51 having a bent configuration as well as an inner surgical element 3, better seen in figure 6, also having a preformed bend, it is unclear as to whether the duodenoscope has a fixed curve therein. The examiner considers it to have been obvious to image the Cho device in various configurations during insertion into the passages of interest since radiopaque markers are provided to do so.

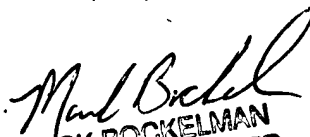
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W Bockelman whose telephone number is (703)-308-2112. The examiner can normally be reached on Monday - Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-305-3591 for regular communications and (703)-306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.

MWB

May 5, 2003


MARK BOCKELMAN
EXAMINER